



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

August 21, 2002

Kristen K. Hughes, Esq.
SG&A Consulting, Inc.
1701 E. Lamar Blvd., Ste. 160
Arlington, TX 76006

Dear Ms. Hughes:

Your petition requesting the Food and Drug Administration to issue an advisory opinion on whether FDA regulations on medical device classification and resulting manufacturer responsibility for data and image archiving technology, was received by this office on 08/21/02. It was assigned docket number 02A-0379/AP 1 and it was filed on 08/21/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

02A.0379

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